K090469
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510(k) Summary

May 20, 2009

MAY 22 2009

CARESTREAM Health, Inc.
150 Verona Street
Rochester NY 14608

Contact: Gayle Carroll
1 Imation Way
Oakdale, MN 55128
Phone: 651-393-1501
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Device

Trade name:	CARESTREAM DRYVIEW 5850 Laser Imager
Common name:	Laser Printer
Classification name:	Medical Image Hardcopy Device (21 CFR 892.2040)

Predicate device Kodak DRYVIEW 8900 Laser Imager with Mammography Accessory (K033821)

Description and Intended Use of Device

The CARESTREAM DRYVIEW 5850 Laser Imager is intended to provide high-resolution hard copy images from digital imaging source output signals. The device is intended for use with KODAK DRYVIEW media including DVM (DryView mammography) films. The imager will interface with a variety of digital modalities, including, but not limited to, CR (Computed Radiology), DR (Digital Radiology), CT (Computerized Tomography), MRI (Magnetic Resonance Imaging) and FFDM (Full Field Digital mammography). Image resizing is used to preserve true geometric size images. The images are to be used for medical diagnosis and referral to physicians and their patients.

Technological Characteristics

The subject device and predicate devices use the same technical design base. The printers receive image data from the modality. User control is performed directly by the modality or through the host control. KODAK DRYVIEW imaging media is removed from a daylight cartridge and transported to the laser imaging station. Image data and media merge at the laser station and the film is scanned. The exposed media is transported through the integrated processor and exits the printer.

Software is used to control the image management and machine functions. AIQC (Automated Image Quality Control) matches printing power with film characteristics to provide consistently high image quality.

Performance Data

Safety and effectiveness are assured via meeting voluntary standards, including: DICOM, SMPTE, UL 60950, IEC 60601-1-1, IEC 60825-1, ISO 12207 and ISO 14971.

Conclusion

The subject device, like the predicate, has no patient contact. The device does not control, monitor or otherwise affect any devices directly connected to or affecting the patient. Medical personnel review images displayed by the subject device and its predicate. This offers ample opportunity for competent human intervention in case of a malfunction or other failure.

The subject CARESTREAM DRYVIEW 5850 Laser Imager and predicate device KODAK DRYVIEW 8900 with Mammography Accessory have both been designed to the equivalent safety standards. As with the predicate device, a test pattern generator and automatic image quality control (AIQC) system are incorporated to assure consistency between input signals and output density. Both are high resolution printers with incorporated test patterns to assist in MQSA quality assurance testing.

Carestream Health therefore concludes that the CARESTREAM DRYVIEW 5850 Laser Imager is as safe and effective as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 22 2009

Ms. Gayle Carroll
Regulatory Affairs Manager
Carestream Health, Inc.
1 Imation Way, 304-4B-28
OAKDALE MN 55128-3414

Re: K090469
Trade/Device Name: Carestream DRYVIEW 5850 Laser Imager
Regulation Number: 21 CFR 892.2040
Regulation Name: Medical image hardcopy device
Regulatory Class: II
Product Code: LMC
Dated: February 20, 2009
Received: February 23, 2009

Dear Ms. Carroll:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

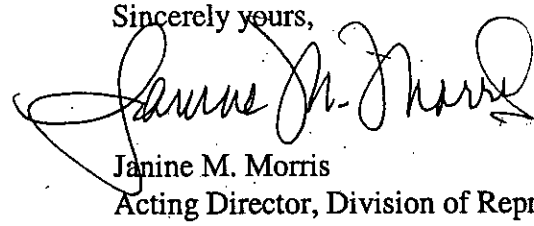
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use:

510(K) Number (if known): K090469

Device Name: Carestream DRYVIEW 5850 Laser Imager

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Prescription Use ✓ AND/OR Over-The-Counter Use____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K090469